

REMARKS

1. STATUS OF THE CLAIMS

Claims 1-19 were originally filed. Claims 1-6 and 15-19 were previously withdrawn as being directed to a non-elected invention. Thus, Claims 7-14 are under examination.

Previously-withdrawn Claims 1-6 and 15-19 are currently canceled. This cancellation was previously proposed by the Examiner as part of the amendments to place the application in condition for allowance, and was accepted in Applicants' June 3, 2011 facsimile to the Examiner.

Claim 7 is currently amended by changing the recitation in step a) of "(RHD) listed as SEQ ID NO:62" to "domain (RHD) comprising SEQ ID NO:62. Claim 7 is also currently amended by canceling "comprising RelB RHD listed as SEQ ID NO:62" from step b), and replacing "said SEQ ID NO:62" with "said polypeptide" in step c). Each of these amendments were previously proposed by the Examiner as part of the amendments to place the application in condition for allowance, and was accepted in Applicants' June 3, 2011 facsimile to the Examiner.

Claims 13 and 14 are currently amended as previously proposed by the Examiner as part of the amendments to place the application in condition for allowance, and was accepted in Applicants' June 3, 2011 facsimile to the Examiner. More particularly, Claims 13 is currently amended by canceling the recitation of "(g) RelB RHD, (h) RelB, and (i) RelB:p50."

Claim 14 is currently amended by replacing "RelB RHD listed as SEQ ID NO:62" with "RelB RHD comprising SEQ ID NO:62." Claims 13 and 14 are currently amended to add the recitation "wherein said unaltered binding indicates specific binding of said nucleotide sequence with said polypeptide." Exemplary support for this amendment of Claim 13 is in the Specification under the heading "I. Detection of **specific binding**, and screening test compounds, using reporter gene assays", (Emphasis added) pages 52-55, and in particular, the teaching:

"The level of **specific binding** of the isolated nucleotide sequence that contains the invention's RelB κ B sequences (*e.g.*, SEQ ID NO:57) with the protein RelB RHD, as exemplified by SEQ ID NO:62, may be determined using reporter gene assays."
(Emphasis added) Specification, page 52, lines 26-30.

Exemplary Support for this amendment of claim 14 is in the Specification under the heading "I. Detection of **specific binding**, and screening test compounds, using reporter gene assays', (Emphasis added) pages 52-55, and in particular, the teaching:

"Alternatively, **one control** involves using the consensus- κ B sequence by detecting unaltered binding of an isolated nucleotide sequence comprising the consensus- κ B sequence 5'-GGGACTTCC-3' (**SEQ ID NO:58**) to a polypeptide comprising one or more of RelB RHD, as exemplified by **SEQ ID NO:62**, and RelB in the presence of the one or more test compounds." (Emphasis added) Specification, page 55, lines 26-30.

Claim cancellations and amendments were made to describe particular embodiments of the invention, notwithstanding Applicants' belief that the un-amended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the canceled and/or un-amended (or similar) claims in another application, but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).¹

2. **WITHDRAWN REJECTIONS**

Applicants note, with appreciation, that the Examiner withdrew the prior rejection of Claims 7, 8, 10, 11, 13 and 14 under 35 U.S.C. §102(b) for alleged anticipation by Saccani *et al.* (Molecular Cell, 2003 11:1563-1574).²

3. **REJECTION OF CLAIMS 7, 8, 10, 11, 13 AND 14 UNDER 35 U.S.C. §102(a) OVER SACCANI *et al.***

Claim 7, 8, 10, 11, 13 and 14 are newly rejected under 35 U.S.C. §102(a) for alleged anticipation by Saccani *et al.* (Molecular Cell, 2003 11:1563-1574).³ Applicants respectfully disagree because Saccani *et al.* is not prior art under 35 U.S.C. § 102(a). Under patent law,

¹ 65 Fed. Reg. 54603 (September 8, 2000).

² Office Action, page 2.

“A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, **before the invention** thereof by the applicant for patent.”⁴

Priority of invention may be demonstrated by a declaration under 37 C.F.R. §1.131 in order “to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.”⁵

Applicants previously submitted a Declaration by Dr. Karin to antedate the Saccani *et al.* reference, which Applicants believed had an earliest publication date of July 3, 2003. However, the Examiner has now provided a document showing that Saccani *et al.* was published on **June 3, 2003**.⁶

The enclosed Declaration by Dr. Karin demonstrates invention by Applicants prior to Saccani *et al.*’s June 3, 2003 publication date. In particular, the enclosed Declaration by Dr. Karin as supported by its Exhibit A, explain that, “**prior to June 3, 2003**,” the co-inventors completed experiments in which they demonstrated the “previously unknown” specificity⁷ of sequences of different κ B sites that are encompassed by the claims’ recited 5’-NGGAGANNTG-3’ (SEQ ID NO:57).⁸ The Declaration further describes competition experiments in which DNA sequences containing the claims’ recited 5’-NGGAGANNTG-3’ (SEQ ID NO:57) were contacted with polypeptide sequence RelB:p52 that contains the claims’ recited Rel homology domain listed as SEQ ID NO:62.⁹ This contacting was performed in the presence and absence of competitive sequences (i.e., sequences encompassed by the claims’ recited “test compounds”), and was followed by determining the level of binding of the DNA sequences with the polypeptide sequences.¹⁰

³ Office Action, page 2.

⁴ 35 U.S.C. § 102(a).

⁵ 37 C.F.R. §1.131; MPEP §715

⁶ Office Action, page 5.

⁷ Dr. Karin’s Declaration, paragraph 8.

⁸ Dr. Karin’s Declaration, paragraph 7, refers to the exemplary sequences GGGACTTTCC, GGGAGATTTG, AGGAGATTTG, and GGGATTTCCTC.

⁹ Dr. Karin’s Declaration, paragraph 8.

¹⁰ *Id.*

In view of the above, the co-inventors invented the subject matter of the claims **prior** to the June 3, 2003 publication date of Saccani *et al.* Thus, Saccani *et al.* is **not** prior art under 35 U.S.C. §102(a).

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 7, 8, 10, 11, 13 and 14 under 35 U.S.C. §102(a) over Saccani *et al.*

4. **REJECTION OF CLAIM 12 UNDER 35 U.S.C. §103(a) OVER SACCANI *et al.* IN VIEW OF TOLEDANO *et al.***

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) for allegedly being obvious over Saccani *et al.* in view of Toledano *et al.* (PNAS, 1991 88:4328-4332).¹¹ Applicants respectfully traverse.

The primary reference Saccani *et al.* is not prior art under 35 U.S.C. §103(a). The Examiner is respectfully reminded that to be prior art under 35 U.S.C. §103, a reference must first qualify as prior art under 35 U.S.C. §102(a), (b), (e), (f), or (g).¹²

However, as discussed above, Saccani *et al.* is not prior art under §102(a).

Saccani *et al.* is also not prior art under §102(b) because the Examiner was persuaded by Applicant's prior arguments that Saccani *et al.*'s June 3, 2003 publication date was not more than a year before the October 1, 2003 filing date of the priority provisional application number 60/508,349.¹³

In addition, Saccani *et al.* also is not prior art under §102(e) because it is not a patent or patent application. Moreover, Saccani *et al.* is not prior art under either §102(f) or §102(g) because there are no facts supporting either derivation under §102(f) or interference under §102 (g).

Since Saccani *et al.* is not prior art under any one of §102(a), (b), (e), (f), or (g), it cannot be prior art under §103. Therefore, the disclosure of Saccani *et al.* is irrelevant.

This leaves the disclosure of Toledano *et al.* However, Toledano *et al.* fails to disclose or suggest contacting an isolated nucleotide sequence comprising 5'-NGGAGANNTG-3'

¹¹ Office Action, page 3, final paragraph.

¹² *In re Bass*, 474 F.2d 1273, 177 USPQ 178 (CCPA 1973), *OddzOn Products Inc. v. Just Toys Inc.*, 43 USPQ2d 1641, 1646 (Fed. Cir. 1997).

¹³ Office Action, page 2.

(SEQ ID NO:57) with a polypeptide sequence comprising RelB Rel homology domain (RHD) SEQ ID NO:62 in the presence and absence of one or more test compounds, and determining the level of specific binding of said nucleotide sequence with the SEQ ID NO:62. This negates obviousness.

In view of the above, Applicants respectfully request that the Examiner withdraw the rejection of Claim 12 under 35 U.S.C. §103(a) over Saccani *et al.* in view of Toledano *et al.*

5. **REJECTION OF CLAIMS 13 AND 14 UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

The Examiner rejected Claims 13 and 14 under 35 U.S.C. §112, second paragraph, for alleged indefiniteness,¹⁴ on the basis that “it is unclear what the recited further step accomplishes.”¹⁵

Claims 13 and 14 are currently amended to add the recitation “wherein said unaltered binding indicates specific binding of said nucleotide sequence with said polypeptide.” This amendment was previously proposed by the Examiner to overcome this rejection, and was previously accepted in Applicants’ June 3, 2011 facsimile to the Examiner.

In view of the above, Applicants respectfully request that the Examiner withdraw the rejection of Claims 13 and 14 under 35 U.S.C. §112, second paragraph.

CONCLUSION

Applicants respectfully request reconsideration of the application in view of the above, which places the claims in condition for allowance. To expedite prosecution, Applicants also respectfully invite the Examiner to **call the undersigned before drafting another written communication**, if any.

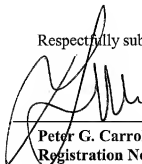
¹⁴ Office Action, page 5, final paragraph.

¹⁵ Office Action, page 6, 1st paragraph.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. **08-1290**.

Respectfully submitted,

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